

REMARKSElection/Restrictions

Applicants traverse the restriction requirement. The examiner argues that claim 28 is independent and distinct from the invention originally claimed because

it is drawn to a process for making an excipient comprising spray drying or extrusion, where the extrusion process comprises a liquid oil. However the extrusion process is recited as an alternative and not a requirement of the claim.

Contrary to the examiner's assertion, the extrusion process does not comprise a liquid oil; the free-flowing powder excipient comprises a liquid. Claim 28, which depends on claim 25, merely provides that "the liquid is an oil."

It is respectfully requested that the examiner reconsider claim 28 and withdraw the restriction requirement.

REJECTIONS UNDER 35 U.S.C. §103

Claims 10 – 12, 14, 17 – 27 stand rejected under 35 U.S.C. §103(a) stand rejected as allegedly being obvious over Ball et al. (US 6,063,865) and Guzi Jr. et al. (US 4,127,422)

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."¹

The combination of references fails to teach or suggest the amount of excipient

The references fail to teach or suggest an excipient consisting essentially of a pharmaceutically acceptable polymer and from 10 to 50% by weight, based on the total weight of said excipient, of a liquid or semisolid solubilizing surface-active substance.

¹ MPEP §2143.

The combination of references fails to teach or suggest this claim limitation.

Ball et al. is directed to a powder composition comprising polymers a), polymers b), and compounds c), as stated at column 2, indicated lines 5 – 25:

The invention provides a crosslinkable powder composition which is redispersible in water and comprises

- a) from 30 to 95 parts by weight of one or more water-insoluble, film-forming polymers ...
- b) from 5 to 70 parts by weight of one or more water-soluble polymers ...
- c) one or more compounds containing at least two functional groups which are present in salt form ...

Ball et al. at column 5, indicated lines 52 – 53 state:

The water-insoluble polymers a) are preferably prepared using the emulsion polymerization process.

Ball et al. at column 6, indicated lines 4 – 8 state:

As dispersants, it is possible to use all emulsifiers customarily employed in emulsion polymerization. Suitable emulsifiers include anionic, cationic and also nonionic emulsifiers. The emulsifiers are preferably used in an amount of up to 6% by weight, based on the total weight of the monomers.

Thus it is clear that the weight percentage of emulsifiers disclosed is based on the total weight of the monomers in the polymers a). It must be noted, however, that Ball et al.'s excipient also comprises polymers b) and compounds c).

At best, Ball et al. suggest a weight percentage of emulsifiers in the excipient of between 1.8 to 5.7% by weight. Yet, on page 4 of the present Office action, the examiner states:

It is the position of the examiner that the determination of these ranges is well within the level of ordinary skill in the art and can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

The examiner is respectfully reminded that “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.”²

Ball et al. provides no teaching which would have enabled a skilled artisan to have recognized the concentration of surfactant in polymer a) of the excipient as a variable that would effect a particular result other than aiding the emulsion polymerization of the polymers a). Moreover, Ball et al. specifically teaches that the total amount of emulsifier in the excipient should never exceed 5.7% by weight, by stating that “[t]he emulsifiers are preferably used in an amount of up to 6% by weight based on the total weight of the monomers.”³ Clearly, Ball et al. fails to teach any result-effectivity of increasing the concentration of surfactant beyond the prescribed maximum concentration.

The disclosure Guzi, Jr. et al. does not compensate for this shortcoming. Guzi, Jr. et al. discloses “[d]ry pigment compositions ... contain[ing] ... a pigment and ... a nonionic material comprising ... a nonionic dispersing agent and ... a water-dispersible, at least partially hydrolyzed polymer of vinyl acetate or a polymer of an N-vinyl pyrrol-idone.”⁴

Guzi, Jr. et al. at column 3, indicated lines 44 – 51 state:

² MPEP § 2144.05, citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

³ US 6,063,865, col. 6, indicated lines 7 – 9 (emphasis added).

⁴ US 4,127,422, abstract.

The amount of nonionic dispersing agent necessary will, as stated, fall within the range of 15 to 45% by weight of the pigment and sufficient dispersing agent must be present to provide ease of processing and particle size reduction. Usually, an amount between about 15 and about 35% by weight of the pigment will provide good dispersibility without detriment to any other desirable properties.

The fact that the range of weight percentages of surfactants in Guzi, Jr. et al.'s pigment compositions falls within the claimed range of 10 to 50% is irrelevant, because that fact would not have been known to a skilled artisan at the time the invention was made. The references, on their own, must have provided the teachings necessary to obviate the claimed invention. "It is impermissible to use the claimed invention as an instruction manual or template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."⁵ At the time the invention was made, a skilled artisan would have understood these references much differently than does the examiner, because that skilled artisan would not have had the benefit of applicants disclosure. Guzi, Jr. et al. would not have taught a skilled artisan that adding more and more surfactant to any given composition is an effective way to achieve a result. A skilled artisan would have understood that when making the pigment compositions of Guzi, Jr. et al. a certain concentration of surfactant is to be used, and when making the powder composition of Ball et al. a certain concentration of surfactant is to be used.

The present application discloses and claims a novel and unobvious process for making an excipient for use in a solid pharmaceutical dosage form. "Once [applicant] had taught how this could be done, the redesign may, by hindsight, seem to be obvious to one having ordinary skills in the ... art. However, when viewed as of the time [applicant's] invention was made, and without the benefit of [applicant's] disclosure ... nothing in the art of

⁵ *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780, 1784 (Fed. Cir. 1992) (quoting *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988)).

record ... suggests [applicant's invention]."⁶

The combination of references fails to teach or suggest all of the claim limitations with regard to the pharmaceutically acceptable polymer

The references fail to teach or suggest that, in addition to the surfactant, the excipient consists essentially of a pharmaceutically acceptable polymer, wherein the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone, which is a water-soluble polymer with Fikentscher K values of from 12 to 100.

It seems that the examiner has overlooked this feature of the claimed invention. The examiner is respectfully reminded of MPEP §2141.02's teaching that "[a]scertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole."

The examiner has not considered Ball et al. as a whole

The examiner impermissibly cherry-picked distinct aspects from Ball et al. in order to construct the rejection, failing to consider the reference as a whole. The Federal Circuit in *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n.5 (Fed. Cir. 1986) stated that "references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination." In this regard, the Examiner considered only parts of Ball et al. picking and choosing only disclosures allegedly favorable for establishing prima facie obviousness.

Ball et al. at column 2, indicated lines 5 – 25 state:

⁶ *In re Ratti*, 270 F.2d 810, 123, 123 USPQ 349 at 352 (C.C.P.A. 1959).

The invention provides a crosslinkable powder composition which is redispersible in water and comprises

- a) from 30 to 95 parts by weight of one or more water-insoluble, film-forming polymers ...
- b) from 5 to 70 parts by weight of one or more water-soluble polymers ...
- c) one or more compounds containing at least two functional groups which are present in salt form

In other words, Ball et al. is directed to a powder composition comprising polymers a), polymers b), and compounds c). Yet, the examiner stated:

The '865 patent discloses a process for making a free-flowing excipient carrier comprising a water-soluble polymer and other ingredients (abstract, col. 2, lin. 1-4).

Thus, the examiner has clearly focused on only one component of the powder composition disclosed in Ball et al., i.e. the polymers b). Perhaps this misdirected focus is due to a misreading of claim 10. Claim 10 recites:

A process for producing an excipient ... wherein said excipient ... consists essentially of

a pharmaceutically acceptable polymer and

... a liquid or semisolid solubilizing surface-active substance,

wherein the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone, which is a water-soluble polymer with Fikentscher K values of from 12 to 100; which comprises....

The examiner is respectfully reminded that "to support [a] conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been

obvious in light of the teachings of the references.”⁷

In order to arrive at what is presently claimed, a skilled artisan would have needed some teaching, suggestion or motivation to eliminate, at the least, polymer a) from Ball et al.’s powder composition comprising polymers a), polymers b), and compounds c).

The examiner has pointed to no teaching, suggestion or motivation for a person of ordinary skill in the art to have eliminated the polymers a) from the powder composition. Thus, the examiner has failed to establish a prima facie case of obviousness, because a combination of the cited references would not have resulted in the presently claimed invention, due, at least, to the inclusion of the polymers a).

No suggestion or motivation existed to eliminate the polymers a) from Ball et al.’s powder composition

Again, Ball et al. is directed to a powder composition comprising polymers a), polymers b), and compounds c). Upon reading and considering the entire disclosure of Ball et al., a skilled artisan would understand that Ball et al. stress the importance of the water-insoluble polymers a) by providing examples of applications in which the powder compositions are useful. More specifically, a skilled artisan would understand the importance of the water-insoluble polymers a), when Ball et al. disclose that their powder compositions are intended to be used

...in chemical building products in combination with inorganic, hydraulic binders such as cements (Portland, alumina, pozzolanaic, slag, magnesia or phosphate cement), plaster of Paris, water glass, for the production of building adhesives, plasters and renders, knifing fillers, screeds, jointing mortars and paints. It can also be used as sole binder for coating compositions and adhesives or as binder for textiles and paper.

In other words, not only do Ball et al. state that their powder composition must include

⁷ *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

polymers a), but Ball et al. also stress the importance of the polymers a). Thus, no teaching, suggestion, or motivation existed to exclude the polymers a) upon making the examiner's proposed combination with Guzi, Jr. et al.

No suggestion or motivation existed to include surfactants, unless Ball et al.'s powder composition comprised the polymers a)

Ball et al. at column 5, indicated lines 52 – 53 state:

The water-insoluble polymers a) are preferably prepared using the emulsion polymerization process.

Ball et al. at column 6, indicated lines 4 – 8 state:

As dispersants, it is possible to use all emulsifiers customarily employed in emulsion polymerization. Suitable emulsifiers include anionic, cationic and also nonionic emulsifiers. The emulsifiers are preferably used in an amount of up to 6% by weight, based on the total weight of the monomers.

The examiner has pointed to no teaching, suggestion or motivation to explain why a skilled artisan would have continued to include a surfactant upon elimination of polymer a). Once the water-insoluble polymer was excluded, a skilled artisan would have had no teaching, suggestion or motivation to continue to include the surfactant. Thus, it was impossible to arrive at the claimed invention based on the teachings of the cited references. Likewise, it is impossible to establish a *prima facie* case of obviousness based on the cited references. Thus, a combination of the cited references is futile. Yet, for the sake of completeness, it is noted that:

No suggestion or motivation existed to combine the cited references

The surfactants utilized in Ball et al. are utilized only as dispersants in the emulsion polymerization of the polymers a). The surfactants utilized in Guzi, Jr. et al. are utilized for a completely unrelated technical purpose. Thus, no suggestion or motivation existed

to combine the cited references.

Finally, applicants note that in the “Response to Arguments” section, the Examiner admits that the Ball et al. reference is “silent ... to the specific surfactants in use and their respective HLB values,”⁸ even though the examiner later contradicts this admission by stating “though the surfactants are present in the [Ball et al.] formulation, the reference is silent to their concentration or HLB values (emphasis added).”⁹ One of ordinary skill in the art would have needed more than simply the concentration and HLB values of the surfactants; the skilled artisan would have needed the surfactants to be identified. The examiner has failed to point to a suggestion or motivation that would have directed a skilled artisan to the particular surfactants utilized in the present invention.

Claims 15 and 16 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ball et al. (US 6,063,865), Shih et al. (US 6,011,096) and Sutton et al. (US 5,993,805)

Applicants submitted arguments in the Reply dated August 2, 2006, but the examiner failed to comment on those arguments. Those arguments are hereby incorporated by reference.

Applicants also reassert that the failings of the Ball et al. reference discussed above, especially with regard to the concentration of surfactant, the presence of polymers a), and the fact that once polymers a) are eliminated a skilled artisan would not have included surfactant.

The application is in condition for allowance.

Favorable action is solicited.

⁸ Page 7, line 10 of the final Office Action of October 23, 2006.

⁹ Page 7, lines 12 and 13 of the final Office Action of October 23, 2006.